## Claims

1. A high purity composition comprising (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one, characterized in that the said composition comprises (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one in an amount less than 0.5%.
2. The composition according to claim 1 characterized in that the amount of (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one is 0.25% or less.
3. The composition according to claim 1 characterized in that the amount of (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one is 0.1% or less.
4. A process for preparing the high purity compositions of claims 1-3 characterized in that crystals of (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one are allowed to age in the presence of water for at least 24 hours.
5. The process according to claim 4 wherein the aging lasts 3-6 days.
6. The process according to claims 4 or 5 characterized in that the crystals are formed in the last step of the Tibolone synthesis comprising the steps of
   a. reacting (7α,17α)-3,3-dimethoxy-17-hydroxy-7-methyl-19-norpregn-5(10)-en-20-yn-3-one in an organic solvent with a weak acidic aqueous solution
   b. pouring out the solution in water which is made slightly alkaline
   c. washing the crystals with water which is made slightly alkaline.
7. A pharmaceutical dosage unit obtainable by admixture of a pharmaceutically suitable solid carrier and the composition according to any one of the claims 1-3.
8. A pharmaceutical dosage unit obtainable by admixture of a pharmaceutically suitable solid carrier and the composition obtainable by the process of claims 4-6.
9. A dosage unit comprising a pharmaceutically suitable solid carrier and (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one in an amount of less than 2.50 mg and having a shelf life specification comprising less than 5% of (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one.
10. The dosage unit according to claim 9 characterized in that (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one is present in an amount of 1.25 mg or less.

11. The dosage unit according to claim 9 characterized in that (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one is present in an amount of 0.625 mg or less.

12. The dosage unit according to claims 9-11 wherein the shelf life is 1.5 , more preferably 2 years.

13. The dosage unit according to claim 9-11 wherein at a shelf life period of 6 months the amount of (7α,17α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one is 3 % or less, more preferably 2% or less.

14. The dosage unit according to claim 13 wherein the shelf life period is 1, preferably 1 ½ year, more preferably 2 years.

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